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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference y01kp-121	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR02/01540**	International filing date *(day/month/year)* 13 AUGUST 2002 (13.08.2002)	Priority date *(day/month/year)* 20 DECEMBER 2001 (20.12.2001)

International Patent Classification (IPC) or national classification and IPC

IPC7 C07D 319/06

Applicant

CHOONGWAE PHARMA CORPORATION et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
18 JULY 2003 (18.07.2003)	30 DECEMBER 2003 (30.12.2003)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR02/01540

I. Basis of the report

1. With regard to the elements of the international application:*

- [X] the international application as originally filed
- [ ] the description:
  pages _____, as originally filed
  pages _____, filed with the demand
  pages _____, filed with the letter of _____
- [ ] the claims:
  pages _____, as originally filed
  pages _____, as amended (together with any statment) under Article 19
  pages _____, filed with the demand
  pages _____, filed with the letter of _____
- [ ] the drawings:
  pages _____, as originally filed
  pages _____, filed with the demand
  pages _____, filed with the letter of _____
- [ ] the sequence listing part of the description:
  pages _____, as originally filed
  pages _____, filed with the demand
  pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [X] the language of publication of the international application(under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained inthe international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages _____
   - [ ] the claims, Nos. _____
   - [ ] the drawings, sheet _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION

International aplication No.
PCT/KR02/01540

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1 - 8	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are referred to:

D1: JP-A-06-107562
D2: US-A-5155251

1. Novelty

D1 and D2 describe preparation methods of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic derivative of Formula I, which is the final product of the present invention. However, the starting materials of the preparation methods in D1 and D2 are different from that of the present invention, which is an epoxide compound of Formula III. In addition, none of D1 and D2 teach β- hydroxyepoxycarboxyilic acid derivative of Formula II, which is the essential intermediate compound of the present invention.

Therefore, the subject matter of claims 1 to 8 seems to be novel (PCT Article 33(2)).

2. Inventive Step

For the analysis of the inventive step, D1 is considered the closest prior art. D2 describes a method of the synthesis of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic acid derivative, starting with 3-hydroxy-4-bromo ester, while the present invention, starting with an epoxide compound of Formula III and preparing β-hydroxyepoxycarboxyilic acid of Formula II through reaction steps a, b, c and D, and then, producing the final product of 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic derivative of Formula 1 by reacting said compound of Formula II through reaction steps e, f and g.

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

As stated above, the final product of the present invention is the same as that of the invention of D1. However, the starting reaction material of the present invention is different from that of the invention of D1, and consequently the reaction mechanisms of both inventions are also different from each other. Accordingly, the difference in the constitution of the present invention is considered to be nonobvious to a person skilled in the art.

Such a difference in preparation method results in another difference: in D1, the reaction temperature is very low, -80℃, while in the present invention, the reaction temperature ranges -20℃ to -30℃, higher than the reaction temperature in D1. Accordingly, the present invention has an effect that it does not need any special reaction device and consequently it is an easy method for mass production.

Therefore, the subject matter of claims 1 to 8 does involve an inventive step in the sense of PCT Article 33(3).

3. Industrial Applicability

Claims 1 to 8 meet the criteria set out in PCT Article 33(4).